



Department of Pesticide Regulation



Mary-Ann Warmerdam
Director

MEMORANDUM

Arnold Schwarzenegger
Governor

TO: Cynthia Oshita
Proposition 65 Implementation
Office of Environmental Health Hazard Assessment

FROM: Jay Schreider, Ph.D. *JSS*
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Medical Toxicology Branch
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DATE: May 15, 2008

SUBJECT: CHEMICALS REQUIRING TESTING (SECTION 14000, 22 CCR)

Christopher Reardon asked that I respond to Alan Hirsch's request for an update to the list of chemicals that have not been adequately tested as required by state law (Section 14000, California Code of Regulations). Since we have worked together in the past on this, I am responding directly to you. Per past convention, I am supplying the update using the version of the list that you provided, with the changes annotated in red ink.

I hope this information meets your needs. If you have any questions, please do not hesitate to contact me.

Attachment

cc: Christopher Reardon, Chief Deputy Director (w/o attachments)
Department of Pesticide Regulation

Alan Hirsch, Chief Deputy Director (w/o attachments)
Office of Environmental Health Hazard Assessment



EXCERPT FROM TITLE 22, CALIFORNIA CODE OF REGULATIONS

§ 14000. Chemicals Required By State Or Federal Law To Have Been Tested For Potential To Cause Cancer Or Reproductive Toxicity, But Which Have Not Been Adequately Tested As Required.

(a) The Safe Drinking Water and Toxic Enforcement Act of 1986 requires the Governor to publish a list of chemicals formally required by state or federal agencies to have testing for carcinogenicity or reproductive toxicity, but that the state's qualified experts have not found to have been adequately tested as required [Health and Safety Code Section 25249.8(c)].

Readers should note that a chemical that already has been designated as known to the state to cause cancer or reproductive toxicity is not included in the following listing as requiring additional testing for that particular toxicological endpoint. However, the "data gap" may continue to exist, for purposes of the state or federal agency's requirements. Additional information on the requirements for testing may be obtained from the specific agency identified below.

(b) Chemicals required to be tested by the California Department of Pesticide Regulation

The Birth Defect Prevention Act of 1984 (SB 950) mandates that the California Department of Pesticide Regulation (CDPR) review chronic toxicology studies supporting the registration of pesticidal active ingredients. Missing or unacceptable studies are identified as data gaps. The studies are conducted to fulfill generic data requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which is administered by the United States Environmental Protection Agency (U.S. EPA). The studies are reviewed by CDPR according to guidelines and standards promulgated under FIFRA. Thus, older studies may not meet current guidelines.

The existence of a data gap for a compound does not indicate a total lack of information on the carcinogenicity or reproductive toxicity of the compound. In some cases, information exists in the open scientific literature, but SB 950 requires specific additional information. A data gap does not necessarily indicate that an oncogenic or reproductive hazard exists. For the purposes of this list, a data gap is still considered to be present until the study is reviewed and found to be acceptable.

Following is a listing of SB 950 data gaps for oncogenicity, reproduction, and teratology studies for the non-200 pesticidal active ingredients. This list will change as data gaps are filled by additional data or replacement studies.

For purposes of this section, "onc mouse" means oncogenicity in mice, "onc rat" means oncogenicity in rats, "repro" means reproduction, "tera rat" means teratogenicity in rats, "tera rabbit" means teratogenicity in rabbits.

Chemical

Testing Needed

Acid Blue 9*

onc rat, onc mouse, repro, tera rat,
tera rabbit

Acid Yellow 23*	onc rat, onc mouse, repro
Agrobacterium radiobacter*	onc rat, onc mouse, repro, tera rat, tera rabbit
Alkyl-1,3-propylene diamine acetate alkyl	tera rat, tera rabbit (only one required)
derived from coconut oil fatty acids	
Alkyl amino-3-amino propane hydroxy,	tera rat, tera rabbit (only one required)
acetate alkyl derived from coconut,	
oil fatty acids	
Ammonium thiosulfate*	onc rat, onc mouse, repro, tera rat, tera rabbit
Borax*	onc rat, repro
Bromadiolone*	onc rat, onc mouse, repro, tera rabbit
Butoxy polypropylene glycol*	onc rat, onc mouse, repro, tera rat, tera rabbit
Butoxy polypropoxy polyethoxy ethanol-	tera rat
iodine complex	
Castor oil*	onc rat, onc mouse, repro, tera rat, tera rabbit
Chlorophacinone*	onc rat, onc mouse, repro
Chromic acid*	onc mouse, repro, tera rabbit
Copper salts of fatty and rosin acids*	onc rat, onc mouse, repro, tera rat, tera rabbit
Disodium octaborate tetrahydrate	onc rat, repro
Menthol*	onc rat, onc mouse, repro, tera rat, tera rabbit
Meta-cresol*	tera rat, onc rat, onc mouse, repro, tera rabbit
Methoprene*	onc mouse, onc rat, repro, tera rat, tera rabbit
Methyl isothiocyanate*	repro
2,2-(Methyl trimethylene dioxy)bis-	onc rat, onc mouse, repro, tera rabbit
(4-methyl-1,3,2-dioxaborinate)*	
Mineral oil*	onc rat, repro, tera rabbit
Muscature*	tera rat, tera rabbit (only one is required)
Petroleum distillates*	onc rat, onc mouse, repro, tera rat, tera rabbit
Petroleum distillates, refined*	onc rat, onc mouse, repro, tera rat, tera rabbit
Petroleum oil, paraffin based*	onc rat, onc mouse, repro, tera rat, tera rabbit
Petroleum oil, unclassified*	onc rat, onc mouse, repro, tera rat,

Polyethoxy polypropoxy polyethoxy ethanol-iodine complex*	tera rabbit tera rat
Propylene oxide*	tera rabbit, repro, tera rat
Sabadilla alkaloids*	onc rat, onc mouse, repro, tera rabbit
Sodium chlorate*	onc rat, onc mouse, repro, tera rabbit
Sodium fluoride*	onc rat, onc mouse, repro, tera rat, tera rabbit
Sodium metaborate	onc rat, repro
Sodium phenate*	tera rat
Tetraglycine hydroperiodide*	tera rat, tera rabbit (only one required)
Triethylene glycol*	onc rat, onc mouse, repro, tera rat, tera rabbit
2,4-Xylenol*	onc rat, onc mouse, repro, tera rat, tera rabbit

*Claims are pending review that data should not be required

(c) Chemicals required to be tested by the U.S. EPA, Office of Toxic Substances.

Under Section 4(a) of the Toxic Substances Control Act, testing of a chemical is required when that chemical may present an unreasonable risk, or is produced in substantial quantities and enters the environment in substantial quantities, or may have significant or substantial human exposure.

For purposes of this section, "tera" means teratogenicity, "rtox" means reproductive toxicity, "onc" means oncogenicity.

<i>Chemical</i>	<i>Testing Needed</i>
Ethylene dichloride	rtox
1,1,2-Trichloroethane	onc, rtox, tera

NOTE: The testing of the above chemicals is being carried out under "Enforceable Consent Agreements" (or ECAs) under Section 4 of TSCA. In addition, there are a number of ongoing TSCA testing action development activities that may be of interest in the context of Proposition 65. When promulgated, these TSCA Section 4 Test Rules and/or ECAs will require industry to conduct reproductive toxicity, developmental toxicity, and/or cancer studies on a number of 1) hazardous air pollutants (or HAPs), 2) chemicals frequently found at Superfund sites, and 3) U.S. high production volume (or HPV) chemicals. As these, and possibly other, TSCA Section 4 Test Rules/ECAs become effective, this table will be revised to reflect those additional chemical substances for which developmental toxicity, reproductive